UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,000	01/24/2005	Daryl Rees	92773	8840

24628 7590 08/17/2010

Husch Blackwell Sanders, LLP
Husch Blackwell Sanders LLP Welsh & Katz
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

EXAMINER	
WEBB, WALTER E	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
08/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,000	REES ET AL.	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/7/2010 has been entered.

Applicants' arguments, filed 5/7/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102--New

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Applezwaig (US 4,680,289).

Applezwaig teaches a method of treating obesity and diabetes obesity syndromes by administering sarsasapogenin (see Abstract; see also Table I at col. 4). The sarsasapogenin is administered orally in tablet form or parentally (see col. 2, lines 55-68). In general, a 70 kilo individual will be administered preferably 50-400 mg (0.71-5.71mg/kg) (see Id).

The reference is anticipatory insofar as the preamble is not limiting, i.e. does not recite "in need thereof". Thus, the claims, as constructed, read on administering the active agent to treat other conditions.

Claim Rejections - 35 USC § 103--previous

Claims 5-7 and 9 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (GB 2 335 599, published 9/29/1999) in view of Roberts (US 4,831,033).

Xia et al. teaches a method of treating conditions that are characterized by a deficiency in the number and function of membrane bound receptors by administering a pharmaceutical composition comprising saponins or sapogenins (see abstract, see also claim 4, at pg. 28). Disease conditions include Alzheimer's disease, senile dementia, Parkinson's disease (**claim 8**), Lambert Eaton disease etc. (see id.). Saponins and sapogenins include sarsasapogenin (**claims 1-5**) (see id. and pg. 28, clm. 3 and 4). The composition is taught to be present with one or more additional active agents (**claim 6**) (see pg. 28, clm. 3). Xia et al. also teaches that the sapogenin compounds treat Alzheimer's disease by selectively increasing muscarinic M_1 receptors (see pg. 23,

lines 23-26), thereby **increasing the activity of the neurotransmitter acetylcholine** (see pg. 2, lines 5-21).

Xia et al. differs from the instant claims insofar as it does not teach treating ALS.

Roberts teaches that Alzheimer's disease is related to ALS and that they both may be treated by **increasing the activity of acetylcholine.** Roberts teaches administration of a cholinesterase inhibitor (**claim 7**) for treating ALS (see Summary of the Invention at col. 3, lines 44-52; see also col. 3, lines 14-17).

Roberts does not teach the use of sarsasapogenin.

It would have been obvious to a person having ordinary skill in the art to use the sarsasapogenin of Xia et al. to treat ALS since ALS and Alzheimer's disease are related illnesses that may be treated the same, as taught by Roberts. Since the sarsasapogenin of Xia et al. treats Alzheimer's disease by increasing the activity of acetylcholine through increased muscarinic receptors, the artisan would have reasonably expected it to treat ALS, which is also known to be treated via increased acetylcholine activity.

Furthermore, it is generally prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art. See MPEP 2144.06. Thus, it would have also been obvious to combine the sarsasapogenin of Xia et al. with the cholinesterase inhibitor of Roberts, as per **claim 7**,

to treat ALS, since they would both serve to enhance of nerve function in the ALS patient.

Since Xia et al. recognized the use of the instant components for increasing the activity of acetylcholine, it would have been obvious to adjust the components within the broad range instantly claimed since this is simply a matter of determining result effective amounts of the ingredients beneficially taught by Xia. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Response to Amendment

Applicant submitted data showing the ability of sarsasapogenin to prolong the survival of an ALS mouse model by thirteen days. These results appear to be unexpected. However, the instant claims are not commensurate in scope with these results. Specifically, the instant claims are not limited to treating patients "in need thereof", or reducing motor-sensory neurodegeneration and neuroimpairment. Therefore, the claims read on treating conditions other than ALS. It is also unclear what route of administration, i.e. orally, intravenously, topically, would suffice to yield the disclosed results. Furthermore, the showing of unexpected results was made for a narrow dosage point, i.e." 3mg/kg/day", which may not suffice to overcome the obviousness rejection. See *In re Kollman, 201 USPQ 193, 199* where the court the found that evidence of unexpected results could not be extrapolated to cover the broader claimed range. And use of the term "about" causes the dosage range to read

very broadly. Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support" (see MPEP 716.02(d) quoting *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980). In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range (see MPEP 716.02(d)). Here, it is not clear whether the results occur over the entire dosage range of "about 0.1 to about 25mg/kg bodyweight".

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612